Minutes of the **Thirteenth Meeting of the UKHCDO Executive Committee** held in **Landsdowne Club, London,** on **Friday the 13th November 1998**

PRESENT: **Dr Christopher A Ludlam - Chairman**

Dr P Collins
Dr BT Colvin
Dr D Creagh
Dr PLF Giangrande
Dr CRM Hay
Dr EE Mayne
Dr V Mitchell
Dr T Nokes
Professor G F Savidge
Dr R Stevens
Dr M Winter

1. **Apologies**

Dr. T. Baglin
Ms Anne Campling
Dr S Davies (represented by Dr. D. Creagh)
Dr FGH Hill
Dr P Jones
Prof CA Lee
Prof G Lowe
Dr M McGovern
Dr B. McVerry
Dr KJ Pasi
Dr O Smith
Miss RJD Spooner
Dr. CH Toh
Dr JT Wilde

2. **Minutes of the meeting held on 7th September**

The Minutes of the meeting of 7th September 1998 were passed as a true and correct record.

3. **Matters arising from the minutes**

a) **Recombinant factor IX concentrates** Dr Ludlam agreed that in view of the current shortage of optimal plasma derived factor IX concentrates, he would write to Mr Dobson, Secretary of State for Health, to urge that rIX be made available

as soon as possible. There are two barriers to be overcome. Firstly, although the DOH have implied that additional funding would probably be made available, using the same patient groups as had been established for recombinant VIII, it had yet to formalise this and no additional funding had yet been identified. Secondly, release of the product had been delayed until the manufacturers amended the text of the package insert to draw attention to the pharmacokinetic differences between pdIX and rIX.

b) **Recombinant factor VIII** Dr Ludlam had written to DOH to seek clarification of the funding arrangements for patients using rVIII when they reached the age of 16 since some Health Authorities had refused continued extra funding to maintain these patients on rVIII. No reply had been received. Dr Ludlam had spoken to Charles Lister (successor to Christine Corrigan at DOH). He had again informally indicated that funding for rVIII should continue beyond the 16th birthday.

4) **Availability of plasma derived and recombinant factors VIII and IX**

Dr Ludlam reviewed the current supply situation. Alpha had withdrawn most of its factor VIII and IX because of yeast found in three bottles of human immunoglobin between January and July of this year from batches subsequently never released. Production since July was not being released until the FDA had completed further investigations. The most optimistic estimate from the manufacturer was that supply would be interrupted for six weeks.

There were significant difficulties in obtaining acceptable alternative supplies. Limited supplies of pdVIII from Grifols (Fahndi) were available, but it does do not manufacture factor IX. Centeon was unable to supply Mononine and had only limited supplies of Monoclate, and a prothrombin complex concentrate. Baxter/Immuno were unable to offer additional supplies of either factor VIII or IX. There were no additional supplies of recombinant factor VIII and recombinant factor IX was unavailable. BPL had supplies of Replenate and Replenine, sourced from British plasma, but would probably be unable to supply American plasma sourced Replenine or Replenate until the beginning of 1999 or possibly later. Limited named-patient supplies of Octanine were available.

Professor Savidge said that he had enough stock of factor IX for his patients to last several months. He was making enquiries on behalf of his colleagues to obtain supplies of factor IX from alternative sources. In particular, he had contacted LFB (France) who might be able to supply high purity SD UF IX within 2-6 weeks; The Danish State Serum Institute, had an ion exchange purified IX and the Dutch Red Cross had a monoclonal IX. Executive members were asked what arrangements they had for alternative supplies. Most had encountered no real problem in procuring supplies of factor VIII, most using named-patient supplies of Fahndi. Many were using British plasma sourced Replenine, although some were using named-patient supplies of Octanine. **It was agreed** that should Benifix (rIX) become available on a named-patient basis in the next few weeks, it was UKHCDO recommendation that it should be made available to patients using the priorities outlined in

the current UKHCDO Therapeutic Products Guidelines.

5) **Recombinant factor VIII – strategy for shortage of supply**

In the previous executive meeting and the AGM, the possibility that a critical shortfall in the supply of rVIII might develop in the succeeding few months had been discussed. Professor Savidge suggested that the recently issued US Guidelines, recommending that all haemophilic patients be treated with recombinant VIII, would cause supplies of rVIII to be diverted from other markets leading to a shortage in Europe. It had been suggested at the AGM that a guideline be drawn up outlining a strategy to be adopted for temporarily changing patients back to pdVIII in the event that supply was inadequate for patients currently on rVIII. Dr Ludlam had circulated a draft guideline prior to the meeting and this was discussed.

There was a spectrum of opinions about the likelihood of a shortage or rVIII of sufficient severity for patients to be changed back to pdVIII. Dr Hay pointed out that 60-70% of US haemophilic patients were already treated with rVIII. US patients were now rationed for rVIII in the same way as the rest of the world. Although it was acknowledged that there was considerable unsatisfied demand for rVIII, both in Europe and the US, there were a number of developments over the next few months which would tend to improve the supply situation. These include the imminent opening of Baxter's Thousand Oaks plant, the opening of a second Bayer production facility at Berkley, California in the Spring and the probable licensing of RVIIISQ (Refacto, Genetics Institute) in mid 1999. There was a consensus that although rVIII supply would be restricted for at least 1-3 years, it could probably be managed in such a way that it was unlikely that patients currently using rVIII would have to be changed back to pdVIII. This judgment is contingent on there being no further major interruptions in the supply of rVIII from any manufacturer.

Opinion was divided on the wisdom of issuing a guideline on changing patients back from rVIII to pdVIII under the circumstances. Although many felt that it would be useful to have a contingency plan in place should a shortage develop, others pointed out that such a guideline had the danger that it might encourage the purchasers to think that we had softened our guidance on the universal desirability of rVIII for all patients. Professor Savidge read his letter to his purchasers which outlined his strategy. This included various options to maximise the efficient use of rVIII but no steps to change patients from rVIII to pdVIII. There seemed no urgency to issue guidelines since a shortage was unlikely to develop for a number of months. A consensus emerged that we should not issue any guidelines at this time but that we should discuss the matter again at the next executive meeting in January. Dr Ludlam would produce an amended and re-titled draft. In the meantime **it was agreed** that there should be a voluntary monitorium on new patients (other than PUPS and those under 16 years) changing to rVIII until the matter had been discussed further in January when the supply situation would be reviewed.

6) **The Letter to Professor Peter Harper**

Following comments from the membership, Dr Ludlam had produced a revised reply to Dr Harper's letter about the UKHCDO Genetics Working Party Guideline. This was tabled and further suggestions for changes should be sent to Dr Ludlam immediately.

7) **Review of UKHCDO Activities**

BT Colvin reviewed the present situation. Anne Campling was to report on UKHCDO Data Collection at the end of the year and then another report on our general activities after that. The UKHCDO had registered under the Data Protection Act.

8) **AOB**

There was none.

9) **Next meeting**

The Landsdowne Club, 25/1/98